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EXAMINER

LI, QIAN J

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 03/10/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/495,947

Applicant(s)

COLEMAN ET AL.

Examiner

Q. Janice Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-29 is/are pending in the application.
- 4a) Of the above claim(s) 4-9, 14-23, 26, 28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 10-13, 24, 25 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

The amendment and response filed 12/20/02 have been entered as paper No. 23. Claim 2 has been canceled. Claims 1, 3, 10, and 24 have been amended. Claims 1, 3-29 are pending, however, claims 4-9, 14-23, 26, 28, and 29 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b). Claims 1, 3, 10-13, 24, 25, and 27 are under current examination.

Please note that previous rejections that have been rendered moot in view of the amendment to claims will not be reiterated; and the arguments presented in Paper No. 23 would be addressed to the extent that they apply to the current rejection.

This application contains claims (claims 4-9, 14-23, 26, 28, and 29) drawn to an invention nonelected with traverse in Paper No. 19. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, and 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "said first happen" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "said first happen" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "said second happen" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 12 and 13 are vague and indefinite because of the claim recitation, "the composition of claim 1 further comprising first and second happens". The composition of the amended claim 1 comprises "at least one non-HBV happen", it is unclear whether it is considered as the "first" happen, whether it is the same or different from the recited "first" in claims 12 and 13, and thus, the metes and bounds of the claims are unclear.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 10-13, 24, 25, and 27 stand rejected under 35 U.S.C. 102(e) as being anticipated by *Birkett et al* (US 6,231,864) for reasons of record advanced in page 9 of paper No. 20, and following.

Amended claims are now drawn to compositions comprising a duck HBV and at least one antigenic non-HBV hapten. This is fully taught by *Birkett*, for example, in column 4, lines 34-41, and table 2 of the cited patent.

In paper No. 23, applicants argue that a closer reading of *Birkett* clarifies that this patent refers to human, and not duck HBV; that *Birkett* generate a particle in which all monomers were modified to include a reactive amino acid sequence, wherein a hapten might be chemically linked to this reactive sequence, but was not otherwise included in the monomer. Applicants also argue that *Birkett* only teaches the insertion of lysine linkage points, the antigenicity of the constructs is never taught or suggested.

In response, *Birkett et al* clearly teach, "THE PHRASE "HBC" AS USED HERE REFERS TO T CELL STIMULATING PROTEINS HAVING AN AMINO ACID RESIDUE SEQUENCE THAT CORRESPONDS TO AN AMINO ACID RESIDUE SEQUENCE ENCODED BY THE HBV NUCLEOCAPSID PROTEIN GENE...SEQUENCES ARE ALSO PROVIDED FOR WOODCHUCK HEPATITIS B CORE PROTEIN AT SEQ ID NO:7...AND DUCK AT SEQ ID NOS: 12 AND 13" (column 7, lines 34-57). Apparently, *Birkett et al* intend to include the duck HBc as one embodiment of the invention.

With respect to claim language, "wherein at least a first portion of said monomers includes at least one non-HBV hapten, and wherein said monomers may be assembled to form a particle" (claim 1), the specification fails to define "include". As indicated in the applicants' argument, "*Birkett generate a particle in which all monomers were modified to include a reactive amino acid sequence*". (underline added by the Examiner) *Birkett* teaches that HBV core protein monomers self-assemble into stable aggregates known as HBV core protein particles, that even after insertion mutations, the HBV core protein still are able to form core particles when foreign epitopes are cloned into the

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immunodominant loop region of HBc, thus could be used as a carrier for linking pathogenic hapten (column 3). Therefore, the chemically modified monomers of *Birkett* are capable of self-assembled to form a particle and include at least one non-HBV hapten. Moreover, the specification teaches, "*In another aspect of the present invention, the foreign, non-duck haptens may be attached to the particle rather than genetically engineered into the monomer sequence. The individual polypeptide haptens can be operatively linked to the particle through an amino acid residue side chain to form an immunogenic conjugate,...*" (Specification, paragraph bridging pages 28 and 29). Clearly, claims as written encompass chemical modification of a duck HBc in light of the disclosure as originally filed.

With respect to the type of chemical modification and antigenicity, *Birkett* teaches, "A STRATEGICALLY MODIFIED HEPADNAVIRUS CORE PROTEIN PARTICLE OF THE PRESENT INVENTION ...PROVIDES ENHANCED IMMUNOGENICITY TO THOSE LINKED HAPTENS" (column 3, line 64 to column 4, line 2). "TYPICALLY, THE CHEMICALLY-REACTIVE AMINO ACID RESIDUE IS A LYSINE, CYSTEINE, OR HISTIDINE RESIDUE OR A CARBOXYL-CONTAINING RESIDUE..." (column 4, lines 25-41). Apparently, *Birkett* teaches lysine as well as other residue modifications. Therefore, *Birkett* anticipates the instant claims.

Applicants further request the Examiner to point out where *Birkett* enables such a feat, as is the burden of the USPTO under § 102.

In response, it is noted that the compositions in the cited patent and presently claimed are both drawn to a duck HBV comprising at least one non-HBV hapten. MPEP 2112 states, "[O]NCE A REFERENCE TEACHING PRODUCT APPEARING TO BE SUBSTANTIALLY

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IDENTICAL IS MADE THE BASIS OF A REJECTION AND THE EXAMINER PRESENTS EVIDENCE OR REASONING TENDING TO SHOW INHERENCY, THE BURDEN SHIFT TO THE APPLICANT TO SHOW AN OBVIOUS DIFFERENCE". Moreover, MPEP 2112.01 instructs that "PRODUCTS OF IDENTICAL CHEMICAL COMPOSITION CAN NOT HAVE MUTUALLY EXCLUSIVE PROPERTIES." A CHEMICAL COMPOSITION AND ITS PROPERTIES ARE INSEPARABLE". THEREFORE, IF THE PRIOR ART TEACHES THE IDENTICAL CHEMICAL STRUCTURE, THE PROPERTIES APPLICANT DISCLOSES AND/OR CLAIMS ARE NECESSARILY PRESENT. *IN RE SPADA*, 911 F.2D 705, 15 USPQ2D 1655, 1658 (FED. CIR. 1990).

"[T]HE PTO CAN REQUIRE AN APPLICANT TO PROVE THAT THE PRIOR ART PRODUCTS DO NOT NECESSARILY OR INHERENTLY POSSESS THE CHARACTERISTICS OF HIS [OR HER] CLAIMED PRODUCT. WHETHER THE REJECTION IS BASED ON INHERENCY' UNDER 35 U.S.C. 102, ON PRIMA FACIE OBVIOUSNESS' UNDER 35 U.S.C. 103, JOINTLY OR ALTERNATIVELY, THE BURDEN OF PROOF IS THE SAME...[FOOTNOTE OMITTED]." THE BURDEN OF PROOF IS SIMILAR TO THAT REQUIRED WITH RESPECT TO PRODUCT-BY-PROCESS CLAIMS. (QUOTING *IN RE BEST*, 562 F.2D 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)). SEE ALSO *IN RE FITZGERALD*, 619 F.2D 67, 70, 205 USPQ 594, 596 (CCPA 1980) EX PARTE PHILLIPS, 28 USPQ 1302, 1303 (BPBI 1993), AND EX PARTE GRAY 10 USPQ2D 1922, 1923 (BPAI 1989). Such prove requires factual evidence demonstrating that actual, unobvious differences exist (or that the claimed products are functionally different than those taught by the prior art) and to establish patentable differences.

Accordingly, this rejection stands.

### **Conclusion**

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-



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1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li  
Examiner  
Art Unit 1632

QJL  
March 4, 2003



ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER